Remarks and Arguments

Applicants have carefully considered the Office Action dated July 13, 2006 and the references cited therein. Applicants respectfully request reexamination and reconsideration of the application.

Claims 1 has been amended to overcome the rejection under 35 USC 112. These amendments have not been made to distinguish over any reference of record and no narrowing of any corresponding equivalents to which the amended limitations or claim is entitled is intended by these amendments.

As set forth in the prior response, an advantage of the present invention is that the claimed apparatus enables *in vivo* imaging and pressure measurements *across* a lesion or treatment site. The claimed proximal admission port fluidly couples a pressure measurement apparatus to the distal ports ports 41, 41' thereby enabling *in vivo* measurement of the pressure gradient *across* the stent mounting location (Serial No. 09/954,763; page 9, line 9 *et seq*). The claimed proximal admission port further provides an ingress into the fluid channel for *in vivo* delivery of a contrast media, therapeutic agents and other fluids to the distal ports 41, 41', thereby enabling enhanced imaging *across* a lesion and treatment of the patient lumen (Serial No. 09/954,763; page 8, lines 3-14 *et seq*) across a treatment site.

Claims 1-8, 10-11, 13-14, 17-19, 23, 25-26, 28-29 and 31-36 are rejected under 35 USC 103(a) as being unpatentable over US Patent 6,786,918, Krivoruchko et al., hereafter Krivoruchko, already of record, in view of US Patent 6,168,617, Blaeser et al., hereafter Blaeser, already of record. Instead, the Examiner is relying on the disclosure in Blaeser, particularly figure 4 thereof, showing apertures 52 formed in the outer sheath

Accordingly, Applicants traverse the rejection of claims under 35 U.S.C. §103(a) on the grounds that the Examiner has failed to create a *prima facie* case of obviousness. In accordance with MPEP §2143.03, to establish a *prima facie* case of obviousness 1) the prior art reference (or references when combined) must teach or suggest *all* of the claim limitations; 2) there must be some suggestion or motivation to modify a reference or combine references; and 3) there must be a reasonable expectation of success.

First, as a primary bases for traversal of the rejection of the claims, Applicants assert that neither Blaeser nor Krivoruchko provide the required motivation for the combination of their respective teachings, nor could there be a reasonable expectation of success in such combination. The examiner is relying on the flexibility of the Blaeser sheath as the motivation for combining the teachings of Blaeser with Krivoruchko. However, flexibility is not a desired characteristic of an outer sheath which mechanically restrains a stress-induced shape memory device or a heat induced shape memory device. No one of ordinary skill in the art at the time of the invention would want to combine thin flexible outer sheath 28 of the balloon-expandable stent delivery device of Blaeser with the self-expanding stent delivery device of Krivoruchko.

Specifically, the Krivoruchko device is used to deploy a self expanding stent 28 which, as taught, is a hypodermic tube of Nickel-Titanium alloy (Krivoruchko, col. 3, lines 48-49; col. 4, line 66 to col. 5, line 3). Outer shaft 26 of Krivoruchko is placed about the restrained stent (Krivoruchko, col. 5, lines 33-34) and maintains the stent in one or more radially compressed configurations (Krivoruchko, col. 2, lines 30-39). Krivoruchko acknowledges that such protective sheaths prevent further expansion at body temperatures for heat induced shape memory devices or to contain mechanically restrained or stress-induced shape memory devices (Krivoruchko, col. 1, lines 30-35). Accordingly, outer shaft 26 of Krivoruchko, as taught, is preferably a braided composite including a stainless steel wire braid (Krivoruchko, col. 3, lines 37-40). Flexibility is not a desired characteristic of an outer sheath which mechanically restrains a stress-induced shape memory device or a heat induced shape memory device. The thin flexible outer sheath 28 of the balloon-expandable stent delivery device of Blaeser, as taught, preferably comprises PTFE or HDPE with a preferred wall thickness of 0.0005 (Blaeser, col. 4, lines 28-30). Blaeser, expressly teaches that the material of sheath 28 is preferably "thin as possible" (Blaeser, col. 4, lines 31-32) and further expressly states:

> "The thinness of sheath 28 is an important feature of the present invention. It is thin and is only present to protect the stent from catching on the body both during implantation or upon withdrawal if stent is not used."
>
> (Blaeser, col. 5, lines 2-6)

In addition, for self-expanding stents that have been implemented with heat induced shape memory device, it is critical that the stent be isolated from the bloodstream during advancement to the deployment site. The plurality of apertures 52 in the thin flexible outer sheath 28 of Blaeser would allow fluid communication from the bloodstream to the stent immediately upon insertion into the body, thereby causing premature heating of the stent to its shape memory configuration and likely causing premature expansion of the stent. Given the thin nature of the sheath itself and its inability to restrain the expanding stent, undesirable premature deployment could occur at a location that causes great risk and complication to the patient. Accordingly, Applicants respectfully assert that a combination of the thin flexible, perforated outer sheath of Blaeser with the self-expanding stent delivery device of Krivoruchko, would change the principle of operation of the Krivoruchko, and could have potentially disastrous results, due to the thin sheath's inability to restrain the outwardly radial force of the self expanding stent on the sheath during deployment and its inability to prevent premature heating due to bloodstream exposure. Krivoruchko would no longer be capable of deploying self-expanding stent. Accordingly, Applicants respectfully traverse the rejection of the claims for failure to establish a *prima facie* case of obviousness since the Examiner has not stated a proper suggestion or motivation to combine the teachings of Krivoruchko with the teachings of Blaeser, and, that there could be no reasonable expectation of success in the attempted combination of such teachings.

Further, Blaeser and Krivoruchko, whether considered singularly or in combinations do not provide the disclosure of a pair of distal perfusion ports capable of being positioned on either side of a treatment site. Even if the Examiner's contentions regarding Blaeser are valid, which Applicants are not conceding, the combination of such teachings would still not disclose the invention as claimed, particularly a distal fluid exchange opening. The Examiner correctly notes that Krivoruchko fails to include discharge openings in the wall of the outer shift near the proximal and distal end of the stent mounting location. In Blaeser, the distal end of sheath 28 which contains apertures 52 is tucked under elastomeric distal cuff 38. Blaeser does not disclose fluid exchange openings located in distal cuff 38. As such, Blaeser does not disclose a fluid

exchange opening distal of the stent mounting location, and, correspondingly, in light of the examiner's admission regarding Krivoruchko, the combination of Blaeser and Krivoruchko, therefore cannot disclose exchange openings both proximal and distal of the stent mounting location. In light of the foregoing, Applicants respectfully assert that claim 1 is patentable over the combined teachings of Krivoruchko and Blaeser.

Claim 1 has been previously amended to specifrically recite "first and second discharge openings in fluid communication with said fluid channel, the discharge openings being located *proximal and distal of the stent mounting location* and extending through a wall of said outer tubular member to permit fluid flow from said admission port and fluid channel to a patient's lumen" (claim 1, line 20-24; *emphasis added*). Claims 2-8, 10-11, 13-14, 17-19, 23 include all of the limitations of claim 1 and are likewise believed patentable over the combined teachings of Krivoruchko and Blaeser for at least the same reasons as claim 1, as well as for the merits of their own respective limitations.

Claims 33 and 34 have been previously amended similar to claim 1 (claim 33, line 18-22; claim 34, line 18-22). Claims 32 has also been previously amended to recite "at least two of the fluid exchange openings being located *proximal and distal of the stent mounting location*, respectively, and another of the fluid exchange openings being located at the proximal end of the catheter" (claim 32, line 6-11; *emphasis added*). Claim 25 already recites similar limitation language (claim 25, line 12-16). Claims 25, 32- 34, as well as their respective dependent claims, are likewise believed patentable over the combined teachings of Krivoruchko and Blaeser for at least the same reasons as claim 1, as well as for the merits of their own respective limitations.

Applicants believe the claims are in allowable condition. A notice of allowance for this application is solicited earnestly. If the Examiner has any further questions regarding this amendment, she is invited to call Applicants' attorney at the number listed below. The Examiner is hereby authorized to charge any fees or credit any balances under 37 CFR §1.17, and 1.16 to Deposit Account No. 02-3038.

Respectfully submitted,

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